[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration 94549d

San Juan District
Compliance Branch
466 Fernández Juncos
San Juan, Puerto Rico 00901-3223

Telephone: 787-474-9500
FAX: 787-729-6658

February 24, 2004

**WARNING LETTER**
**SJN-04-04**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. Manuel Quintana
President
Quintana Hermanos Inc.
P.O. Box 364706
San Juan, P.R., 00936-4706

Dear Mr. Quintana:

On September 30, 2003, the Food and Drug Administration's (FDA) conducted an inspection of your facility located at Calle San Luis #220, Urb. Industrial Bechara, Puerto Nuevo, PR 00920 and found you have serious deviations from FDA's Seafood HACCP Regulation (21 CFR Part 123).

In accordance with 21 CFR 123.12(g), failure of an importer to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly the fishery products listed below are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or been rendered injurious to health. You can find the Act and Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deficiencies are the following:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under section 402 of the Act because they may be injurious to health or may have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for:
   Salted Pollock Fillets from [redacted]
   Salted O/C Pollock from [redacted]
   Salted O/C Hake from [redacted]
   Salted Cod Fillets from [redacted]

Salted Cod Cellos 20's from [redacted]
S/D Cod from [redacted]
Gaspe Cure Codfish from [redacted]
Bacalao Faroe Curado from [redacted]

2. You must also implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for:

Salted Pollock Fillets shipped by [redacted] in [redacted]
Salted O/C Pollock shipped by [redacted] in [redacted]
Salted O/C Hake shipped by [redacted] in [redacted]
Salted Cod Fillets shipped by [redacted] in [redacted]
Salted Cod Cellos 20's shipped by [redacted] in [redacted]
S/D Cod shipped by [redacted] in [redacted]
Gaspe Cure Codfish shipped by [redacted] in [redacted]
Dried Codfish shipped by [redacted] in [redacted]

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product and/or enjoin your firm from operating. We are aware that our agency issued an untitled letter to you on September 17, 1998 including deviations found during a prior inspection conducted on August 27, 1998. Some of those deviations are similar to those reported during the recent inspection and no action has been taken to correct them.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as a written verification procedure, letter of guarantees, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in further regulatory actions, such as seizure, injunction, or your products being placed on "Detention Without Physical Examination". You can find the U.S. Federal Food, Drug and Cosmetic Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR Part 123) and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the US Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, P.R. 00901-3223, Attention: Margarita Santiago, Compliance Officer.

Sincerely,

Donald J. Voeller
District Director
San Juan District